

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA**

WHOLE WOMAN'S HEALTH ALLIANCE; et al.,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG
ADMINISTRATION; et al.,

Defendants.

Case No. 3:23-cv-00019

EXHIBIT LIST

Exhibit A U.S. Food & Drug Admin., NDA 20-687 Mifeprex Approval Memo, Sept. 28, 2000

Exhibit B U.S. Gov't Accountability Office, GAO-08-751, Food and Drug Administration
Approval and Oversight of the Drug Mifeprex (2008)

Exhibit C: U.S. Food & Drug Admin., Medical Officer's Review of NDA 20-687 (Nov. 1999

Exhibit D: U.S. Food & Drug Admin., FDA-2002-P-0364-0002, Letter from Janet Woodcock,
Dir., Ctr. for Drug Evaluation & Rsch., U.S. Food & Drug Admin., to Donna
Harrison, Exec. Dir., Am. Assoc. of Pro Life Obstetricians & Gynecologists, Gene
Rudd, Senior Vice President, Christian Med. & Dental Ass'n, and Penny Young
Nance, CEO and President, Concerned Women for Am., denying Citizen Petition,
Docket No. FDA-2002-P0364 (Mar. 29, 2016)

Exhibit E: U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., No.
020687Orig1s020, Mifeprex Medical Review(s) 8, 12 (Mar. 29, 2016)

- Exhibit F: U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., Full Prescribing Information for Mifeprex 7–8, tbls.1 & 2 (Mar. 2016)
- Exhibit G: U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., No. 020687Orig1s020, Mifeprex Risk Assessment and Risk Mitigation Review(s): REMS Modification Memorandum 3 (Mar. 29, 2016)
- Exhibit H: U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., No. 020687Orig1s020, Mifeprex Summary Review 15 (Mar. 29, 2016)
- Exhibit I: U.S. Food & Drug Admin., Mifepristone U.S. Post-Marketing Adverse Events Summary through 06/30/2022
- Exhibit J: Letter from Janet Woodcock, Acting Comm'r, U.S. Food & Drug Admin., to Maureen G. Phipps, Chief Exec. Officer, Am. Coll. Of Obstetricians & Gynecologists, and William Grobman, President, Soc'y for Maternal-Fetal Med. (Apr. 12, 2021)
- Exhibit K: Letter from Soc'y of Fam. Plan. et al., to Stephen Ostroff, Acting Comm'r of Food & Drugs, Robert M. Califf, Deputy Comm'r for Med. Prods. & Tobacco & Janet Woodcock, Dir., Ctr. for Drug Evaluation & Rsch., U.S. Food & Drug Admin. 2 (Feb. 4, 2016)
- Exhibit L: U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., No. 020687Orig1s020, Mifeprex Risk Assessment and Risk Mitigation Review(s): Letter from Janet Woodcock, Dir., Ctr. for Drug Evaluation & Rsch., U.S. Food & Drug Admin., Re: NDA 020687, Supp 20 (Mar. 28, 2016)

- Exhibit M: U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., No. 202107Orig1s000, Korlym (mifepristone) Risk Assessment and Risk Mitigation Review(s) (Jan. 27, 2012)
- Exhibit N: Letter from Maureen G. Phipps, Am. Coll. Of Obstetricians & Gynecologists, and James L. Madara, CEO & Exec. Vice President, Am. Med. Ass'n, to Robert Califf, Comm'r, U.S. Food & Drug Admin. 2 (Jun. 21, 2022)
- Exhibit O: Citizen Petition, Docket No. FDA-2022-P-2425, from Am. Coll. Of Obstetricians & Gynecologists et al. to Lauren Roth, Assoc. Comm'r for Pol'y, U.S. Food & Drug Admin. (Oct. 4, 2022)
- Exhibit P: U.S. Food & Drug Admin., FDA-2022-P-2425-0003, Letter from Patrizia A. Cavazzoni, Dir., Ctr. for Drug Evaluation & Rsch., U.S. Food & Drug Admin., to Maureen G. Phipps, Am. Coll. Obstetricians & Gynecologists, denying Citizen Petition, Docket. No. FDA-2022-P-2425 (Jan. 3, 2023)
- Exhibit Q: Letter from Xavier Becerra, Cal. Att'y Gen, et al., to Alex M. Azar, Sec'y, U.S. Dep't of Health & Hum. Servs. & Stephen Hahn, Comm'r, U.S. Food & Drug Admin. (Mar. 30, 2020)